

WE CLAIM:

- 1 1. A solid dosage form comprising:
2 bupropion hydrochloride; and
3 a stabilizer, wherein the stabilizer comprises glucono delta lactone or its
4 corresponding open chain hydroxy acid derivative.
- 1 2. The solid dosage form of claim 1, wherein the bupropion
2 hydrochloride retains at least 80% of the bupropion hydrochloride potency after
3 storage for three months at 40°C and 75% relative humidity.
- 1 3. The solid dosage form of claim 1, wherein the stabilizer is glucono
2 delta lactone.
- 1 4. The solid dosage form of claim 1, wherein the stabilizer is a
2 corresponding open chain hydroxy acid derivative of glucono delta lactone.
- 1 5. The solid dosage form of claim 4, wherein the corresponding open
2 chain hydroxy acid derivative of glucono delta lactone is gluconic acid.
- 1 6. The solid dosage form of claim 1, wherein the concentration of
2 glucono delta lactone or corresponding open chain hydroxy derivative comprises from
3 about 5% to about 100% by weight of the bupropion hydrochloride.
- 1 7. The solid dosage form of claim 1, wherein the concentration of
2 glucono delta lactone or corresponding open chain hydroxy derivative comprises from
3 about 5% to about 50% by weight of the bupropion hydrochloride.
- 1 8. The solid dosage form of claim 1, wherein the amount of bupropion
2 hydrochloride comprises between about 25 and about 500 mg w/w of the solid dosage
3 form.
- 1 9. The solid dosage form of claim 1, wherein the solid dosage form
2 comprises one or more of a tablet, a capsule, and a granulate with or without an
3 immediate release profile, a modified release profile, or an extended release profile.
- 1 10. The solid dosage form of claim 9, wherein the solid dosage form
2 comprises a tablet.

1 11. The solid dosage form of claim 10, wherein the tablet comprises a
2 sustained release tablet.

1 12. The solid dosage form of claim 9, wherein the solid dosage form
2 comprises a capsule.

1 13. The solid dosage form of claim 12, wherein the capsule comprises a
2 sustained release capsule.

1 14. The solid dosage form of claim 1, further comprising one or more
2 pharmaceutically acceptable excipients comprising one or more of rate controlling
3 polymers, diluents, binders, disintegrants, lubricants, glidants, and coloring agents.

1 15. The solid dosage form of claim 14, wherein the release rate controlling
2 polymers comprises one or more of cellulose derivatives, acrylates, a mixture of
3 polyvinylacetate and povidone, polyethylene oxides, starch and its derivatives, gums,
4 alginates, carbohydrate based polymers, and polysaccharide.

1 16. The solid dosage form of claim 14, wherein the cellulose derivative
2 comprises one or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,
3 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, and
4 sodium carboxymethylcellulose.

1 17. The solid dosage form of claim 16, wherein the cellulose derivative
2 comprises hydroxypropyl cellulose.

1 18. The solid dosage form of claim 14, wherein the diluent comprises
2 microcrystalline cellulose.

1 19. The solid dosage form of claim 14, wherein the lubricant comprises
2 stearic acid.

1 20. A process for preparing a solid dosage form of bupropion
2 hydrochloride, the process comprising;

3 mixing bupropion hydrochloride and a stabilizer to form a blend, wherein the
4 stabilizer comprises glucono delta lactone or its corresponding open chain hydroxy
5 acid derivative; and

6 forming the blend into a solid dosage form.

1 21. The process of claim 20, wherein the solid dosage form retains at least
2 80% of the bupropion hydrochloride potency after storage for three months at 40°C
3 and 75% relative humidity.

1 22. The process of claim 20, wherein the stabilizer is glucono delta
2 lactone.

1 23. The process of claim 20, wherein the stabilizer is a corresponding open
2 chain hydroxy acid derivative of glucono delta lactone.

1 24. The process of claim 23, wherein the corresponding open chain
2 hydroxy acid derivative of glucono delta lactone is gluconic acid.

1 25. The process of claim 20, wherein the concentration of glucono delta
2 lactone or corresponding open chain hydroxy derivative comprises from between
3 about 5% to about 100% by weight of bupropion hydrochloride.

1 26. The process of claim 25, wherein the concentration of glucono delta
2 lactone or corresponding open chain hydroxy derivative comprises from between
3 about 5% to about 50% by weight of bupropion hydrochloride.

1 27. The process of claim 20, wherein the amount of bupropion
2 hydrochloride comprises from between about 25 to about 500 mg w/w of the solid
3 dosage form.

1 28. The process of claim 20, wherein forming the blend into a solid dosage
2 form comprises forming a tablet, capsule or granulate with or without an immediate
3 release profile, a modified release profile, or an extended release profile.

1 29. The process of claim 28, wherein the solid dosage form comprises a
2 tablet.

1 30. The process of claim 29, wherein the tablet comprises a sustained
2 release tablet.

1 31. The process of claim 28, wherein the solid dosage form comprises a
2 capsule.

1 32. The process of claim 31, wherein the capsule comprises a sustained
2 release capsule.

1 33. The process of claim 20, wherein the mixing comprises wet
2 granulation.

1 34. The process of claim 20, wherein the mixing comprises dry
2 granulation.

1 35. The process of claim 20, wherein the mixing comprises direct
2 compression.

1 36. The process of claim 20, wherein the solid dosage form further
2 comprises one or more pharmaceutically acceptable excipients selected from rate
3 controlling polymers, diluents, binders, disintegrants, lubricants, glidants and coloring
4 agents.

1 37. The process of claim 36, wherein the release rate controlling polymer
2 comprises one or more of cellulose derivatives, acrylates, a mixture of
3 polyvinylacetate and povidone, polyethylene oxides, starch and their derivatives,
4 gums, alginates, carbohydrate based polymers, and polysaccharide.

1 38. The process of claim 37, wherein the cellulose derivative comprises
2 one or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,
3 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, and
4 sodium carboxymethylcellulose.

1 39. The process of claim 38, wherein the cellulose derivative comprises
2 hydroxypropyl cellulose.

1 40. The process of claim 36, wherein the diluent comprises
2 microcrystalline cellulose.

1 41. The process of claim 36, wherein the lubricant comprises stearic acid.

1 42. A method of treating either or both of depression and nicotine
2 addiction in a human, the method comprising orally administering to a human in need
3 thereof a solid dosage form comprising bupropion hydrochloride and a stabilizer,
4 wherein the stabilizer comprises glucono delta lactone or its corresponding open chain
5 hydroxy acid derivative.

1 43. The method of claim 42, wherein the bupropion hydrochloride retains
2 at least 80% of the bupropion hydrochloride potency after storage for three months at
3 40°C and 75% relative humidity.

1 44. The method of claim 42, wherein the stabilizer is glucono delta
2 lactone.

1 45. The method of claim 42, wherein the stabilizer is a corresponding open
2 chain hydroxy acid derivative of glucono delta lactone.

1 46. The method of claim 45, wherein the corresponding open chain
2 hydroxy acid derivative of glucono delta lactone is gluconic acid.

1 47. The method of claim 42, wherein the concentration of glucono delta
2 lactone or corresponding open chain hydroxy derivative comprises from about 5% to
3 about 100% by weight of the bupropion hydrochloride.

1 48. The method of claim 42, wherein the concentration of glucono delta
2 lactone or corresponding open chain hydroxy derivative comprises from about 5% to
3 about 50% by weight of the bupropion hydrochloride.

1 49. The method of claim 42, wherein the amount of bupropion
2 hydrochloride comprises between about 25 and about 500 mg w/w of the solid dosage
3 form.

1 50. The method of claim 42, wherein the solid dosage form comprises one
2 or more of a tablet, a capsule, and a granulate with or without an immediate release
3 profile, a modified release profile, or an extended release profile.